

It is noted that on pages 18-33 of the present specification, Applicants have disclosed in detail the cloning and nucleotide sequence of GDF-1 (Example 1), *in vitro* translation (Example 2), Southern blot analysis (Example 3), expression (Example 4), preparation of antisera (Example 5) and purification (Example 6). Furthermore, Applicants have disclosed amino acid sequences for the claimed invention. It is clear from Figure 5 that hamster GDF-1 proteins have been isolated. It is respectfully submitted that using similar techniques, persons of skill in the art would be able to isolate other mammalian GDF-1 proteins. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 4-10 and 22-33 were rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. This rejection is traversed for the following reasons.

It is the Examiner's position that the specification fails to enable how to use the GDF-1 protein without undue experimentation. It is respectfully pointed out that Example 5 details how to prepare antisera against GDF-1. Such antisera can be used to characterize GDF-1 at the protein level, to screen for the presence of GDF, and for many other purposes, as will be appreciated by persons of skill in the art.

Furthermore, Applicant has submitted the Declaration of Ted Ebendal, demonstrating that GDF-1 has biological activity on neurons similar to members of the TGF-beta superfamily of proteins. The Examiner has indicated that this Declaration is insufficient because information presented in the Declaration was not known at the time the application was filed. It is submitted that Applicant stated in the originally filed Declaration that GDF-1 was a new member of the TGF-beta superfamily, and should have similar activities to other members of that family. The evidence presented in the Declaration is in support of that statement, and should thus be accepted for what it demonstrates. Reconsideration is requested.

Applicant does not agree with the Examiner that uses of the claimed invention disclosed in the application and pointed out in Applicant's previous responses are not enabled. Applicant is not arguing that a person skilled in the art would have to "dream up" potential uses of the present invention. Instead, applicant submits that the Examiner has not explained in previous Office Actions why the objective truth contained in the disclosure is doubted by "evidence or reasoning which is inconsistent with the contested statement". M.P.E.P. 2164.01 and *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971). No such evidence or reasoning was given in the previous Office Actions, the Examiner merely stated her

LEE - Appln. No. 08/971,338

belief that "it could not be predicted which activity GDF-1 would have, if any" (page 2 of Paper No. 3). Thus, the Examiner's objection appears to be based on the lack of working examples in the specification. However, applicant submits that working examples are not required in order to comply with Section 112, first paragraph, (M.P.E.P. 2164.02) especially in view of the other examples provided in the specification.

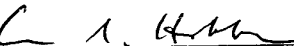
Claims 22-30 were rejected under 35 USC § 112, second paragraph, as being indefinite. Claims 22-24 and 30 have been amended to overcome the rejection. Reconsideration and withdrawal are requested.

All rejections having been addressed, it is respectfully submitted that the application is in condition for allowance, and Notice to that effect is respectfully requested.

Respectfully submitted,

Cushman Darby & Cushman  
Intellectual Property Group of  
PILLSBURY MADISON & SUTRO, L.L.P.

By



Ann S. Hobbs, Ph.D.

Reg. No. 36,830

Telephone: (202) 861-3063

Facsimile: (202) 822-0944

1100 New York Avenue, N.W.  
Ninth Floor, East Tower  
Washington, D.C. 20005-3918  
Phone: (202) 861-3000